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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,199	09/10/2003	Stephen M. Allen	BB1157 US CNT	5569

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/659,199	**Applicant(s)** ALLEN ET AL.	
	Examiner Anne R. Kubelik	**Art Unit** 1638	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 July 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *04/02/2009*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *26-30*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Anne R Kubelik/
Primary Examiner, Art Unit 1638

Continuation of 11. does NOT place the application in condition for allowance because:

112, 1st, written description:

Applicant correctly assumes that this rejection only applies to claims 26-29.

Applicant urges that a requirement that the specification teach the structural elements that confer brittle 1 activity is not the legal standard. This is not found persuasive because Ariad says this IS the legal standard. See Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 94 USPQ2d 1161 (Fed. Cir. 2010) at pg 1171:

For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus…

[M]erely drawing a fence around the outer limits of purposed genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.

Applicant urges that the claimed invention conforms to Example 14 of the Written Description Guidelines and provides more guidance that example 11, because the claimed nucleic acids must encode a protein with brittle-1 activity; they also teach assays, citing Shannon and procedures for producing protein are known in the art. This is not found persuasive because this is merely "describing how to obtain possession of members of a genus", which as Applicant noted in saying that Kubin says that possession may not be shown by merely describing how to obtain possession of members of a genus, does not show possession. Further, neither the specification nor the prior art describe structures required for brittle-1 function.

Applicant urges that the specification does teach the correlation between Brittle-1 activity and DNA sequence in Fig 1 and are not required to teach what is known in the art at the time of filing; Kubin does not disclose any variants, while the instant case does in Fig 1 and provides guidance as to which amino acids could be modified in its sequence comparison to a brittle 1 protein with 57.3% identity; in regions of high homology few substitutions should be made while in regions of low homology many could. This is not found persuasive because Ariad essentially indicates that Applicant must describe what's in that broad generic "black box" in a way that the one of skill in the art can predict (beforehand) what compounds will have that activity. Further, a related protein in Kubin was not sufficient to produce description.

112, 1st, enablement

Applicant correctly assumes that this rejection only applies to claims 26-29.

Applicant urges that any experimentation would be routine and Kubin supports their arguments because the specification teaches how to make variants, calculate sequence identity, and provides an assay. This is not found persuasive because the guidance on pg 15-16 is merely general, and not specific to brittle-1 proteins, and the Shannon assay would be laborious for use in testing variants, if it is even possible to do so. Quoting from the rejection:

The specification fails to provide an assay for Brittle-1 activity. The specification on pg 6, lines 20-21, references Shannon et al (1998, Plant Physiol. 117:1235-1252). In this reference, ADP-glucose uptake was measured in isolated amyloplasts from bt-1 mutants (See paragraph spanning pg 1245-1246). The specification fails to teach how to use this method to assay variant nucleic acids. It is possible Applicant envisions transforming bt-1 mutant maize or a yet unidentified wheat equivalent with nucleic acids encoding the variants, isolating the amyloplasts from the transformants, and measuring ADP-glucose uptake. However, it is not clear that this laborious process would even be possible. Sullivan et al (1995, Planta 196:477-484) teach that the full-length maize Brittle-1 coding region could not be expressed in E. coli (pg 478, left column, paragraph 3).

Applicant has not explained how, in light of this, Shannon's assay could be applied to variants of their protein.

Applicant urges that if their invention is limited to nucleic acids encoding SEQ ID NO:18, their

invention becomes useless because one of skill in the art could make a single amino acid substitution and use Shannon's assay. This is not found persuasive because this would be true regardless of the claim; if it were possible to make the 21 amino acid substitutions required to make a protein with 95% identity to SEQ ID NO:18, then one of skill in the art would be able to design around Applicant's claim and make a protein with 22 amino acid substitutions. The ability of the public to successfully design around - to use the patent disclosure to design a product or process that does not infringe, but like the claimed invention, is an improvement over the prior art - is one of the important public benefits that justify awarding the patent owner exclusive rights to his inventions (ATD Corp. v. Lydall Inc. 43 USPQ2d 1170 (DC EMich 1997), 1178). Notice permits other parties to avoid actions that infringe the patent and to design around the patent (London v. Carson Pirie Scott & Co. 20 USPQ2d 1456 (CA FC 1991), 1458).

Applicant urges that arguments presented in enablement should be applicable towards establishing written description and vice versa and the claims are enabled by definition. This is not found persuasive because written description and enablement are two different standards. See Ariad.

103:

This rejection would apply to claims 26-30

Applicant urges that the sequence of the wheat gene cannot be anticipated by a general statement that it would be obvious to isolate homologs because don the sequence from another plant. This is not found persuasive; the examiner agrees they are not anticipated by it - they are made obvious by it, which is why this is a rejection under 37 CFR 103, not 37 CFR 102.

Applicant urges that Sullivan provides no motivation to search for other monocot brittle-1 genes. This is not found persuasive because there need not be a teaching, suggestion or motivation in the cited art for obviousness. See KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) at pg 1396:

The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way.

Applicant urges that if the BPAI were to hold that the presence of a gene in one plant makes obvious homologs in other organisms, it would be an expansion of obviousness doctrine. This is not found persuasive because this rejection says that a gene in one economically important monocot makes obvious the homolog from another economically important monocot; it does not say it would be obvious to isolate the homolog from all other plants.

Applicant urges that there is no specific motivation in the reference. This is not found persuasive for the reasons above.

Applicant urges that Li does not provide motivation to isolate the gene. This is not found persuasive because there need not be a teaching, suggestion or motivation in the cited art for obviousness.